Data Evaluation Report on the Acute Toxicity of SXX 0665 Technical (JAU6476-desthio) to Rainbow Trout (*Oncorhynchus mykiss*)
PMRA Submission Number 2004-0843 EPA MRID Number 46246020

Data Requirement:		
	PMRA DATA CODE	9.5.2.1
	EPA DP Barcode	D303488
	OECD Data Point	8.2.1
	EPA MRID	46246020
	EPA Guideline	§72-1c

Test material: SXX 0665 Technical **Purity:** 93.7%
Common name: JAU6476-desthio
Chemical name: IUPAC: 2-(1-Chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1, 2, 4-triazol-l-yl)-propan-2-ol
CAS name: 2-(1-Chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1, 2, 4-triazol-l-yl)-propan-2-ol
CAS No.: 120983-64-4
Synonyms: SXX 0665

Primary Reviewer: Rebecca Bryan
Staff Scientist, Dynamac Corporation
Signature:
Date: 8/31/2004

QC Reviewer: Gregory Hess
Staff Scientist, Dynamac Corporation
Signature:
Date: 9/7/2004

Primary Reviewer: Kevin Costello
OPP/EFED/ERB-IV
Date:

Secondary Reviewer(s): Christopher J. Salice
OPP/EFED/ERB-IV Chris J. Salice 6-30-05
Date: 6/30/2005

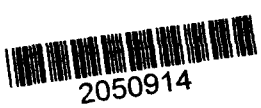
Secondary Reviewer: Émilie Larivière (#1269)
HC, PMRA, EAD
Date: 7/11/2005 7/11/05

Reference/Submission No.: 2004-0843

Company Code: BCZ
Active Code: PRB
Use Site Category: 7, 13, 14
EPA PC Code: 113961

Date Evaluation Completed:

CITATION: Grau, R. 1990. SXX 0665 Technical, Acute Toxicity to the Rainbow Trout in a Static Test. Unpublished study performed by Bayer AG Crop Protection Business Group, Crop Protection Development, Leverkusen, Germany, Laboratory Study No. E 2800441-9, and sponsored by Bayer CropScience, RTP, NC. Experimental start date May 14, 1990 and experimental termination date May 18, 1990. The final report issued October 26, 1990.



EXECUTIVE SUMMARY:

The 96-hour acute toxicity of SXX 0665 Technical (JAU6476-desthio) to Rainbow trout (*Oncorhynchus mykiss*) was studied under static conditions. Fish were exposed to SXX 0665 Technical at nominal concentrations of 0 (negative control), 1.17, 2.34, 4.69, 9.37, and 18.74 ppm a.i. Mean-measured concentrations were 2.22, 4.20, 8.40, and 14.9 ppm a.i. for the nominal 2.34, 4.69, 9.37, and 18.7 ppm a.i. treatment groups, respectively.

After 96 hours of exposure, there was 100% mortality in the 9.37 and 18.74 ppm a.i. treament groups, compared to 10% mortality in the control. There were no mortalities in the 1.17, 2.34, and 4.69 ppm a.i. treatment groups. The calculated 96-hour LC_{50} (with 95% C.I.) was 5.94 (4.20-8.40) ppm a.i., which categorizes SXX 0665 Technical as moderately toxic to Rainbow trout (*Oncorhynchus mykiss*) on an acute toxicity basis. Sub-lethal effects observed during the exposure period included fish mainly at the bottom, lying on side/back, tumbling during swimming, and convulsions (4-96 hours; Table 1, p. 15). After 96-hours of exposure, surviving fish from the mean-measured 4.20 ppm a.i. treatment group were at the bottom, lying on side/back, and tumbling during swimming. The NOAEC and LOAEC values based on sub-lethal effects (most sensitive endpoint) were 2.22 and 4.20 ppm a.i., respectively.

This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with Rainbow trout [§72-1(c)]. This study is classified as ACCEPTABLE.

Results Synopsis

Test Organism Size/Age (mean Weight or Length):	Age not specified; 1.26 ± 0.28 g, 4.80 ± 0.29 cm (mean at the start of the study)
Test Type (Flow-through, Static, Static Renewal):	Static

96-Hour
LC_{50}: 5.94 ppm a.i. 95% C.I.: 4.20-8.40 ppm a.i.
NOAEC: 2.22 ppm a.i.
LOAEC: 4.20 ppm a.i.
Endpoints affected: Mortality and sub-lethal effects
Most sensitive endpoint: Sub-lethal effects

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was based on procedures outlined in EEC Directive 79/831, Annex V, Methods for the determination of Ecotoxicity, Method 5.1.1. Acute Toxicity for Fish (1984); OECD Guideline for the Testing of Chemicals No. 203, "Fish, Acute Toxicity Test" (1984); and U.S. EPA Guideline 72-1 (p. 7). Deviations from §72-1c include:

1. The age of the test organism at test initiation was not specified.
2. The test vessel type, size, and fill volume were not reported.
3. The dissolved oxygen content in terms of percent saturation was not reported.
4. The concentration of particulate matter in the dilution water was not reported.

5. It was not reported whether or not aeration was used during the exposure period.

6. The test solution temperature ranged (12 ± 1°C) lower than the recommended range (13-17°C).

7. Nominal rather than mean-measured treatment concentrations were used to determine all toxicity values.

8. The nominal 1.17 ppm a.i. treatment level was not analytically verified at any time during the 96-hour exposure period (See discussion in Deficiency section below).

The above deviations were considered minor and did not affect the acceptability or validity of this study.

COMPLIANCE: Signed and dated GLP, Confidentiality, and Quality Assurance statements were provided. This study was conducted in compliance with the Principles of Good Laboratory Practice (U.S. EPA, 40 CFR Part 160, 1989; OECD, 1981; and ChemG, 1990) (pp. 1c and 3).

A. MATERIALS:

1. Test Material SXX 0665 Technical (JAU6476-desthio)

Description: Beige-brown powder

Lot No./Batch No. : 17005/89

Purity: 93.7%

Stability of Compound Under Test Conditions: The stability of the test substance in the dilution water during the course of the study was demonstrated by analytical verification at 0, 1, 2, and 4 days. Recoveries were 80-94% of nominal concentrations in Day 0 samples for the nominal 2.34, 4.69, 9.37, and 18.7 ppm a.i. treatment levels, 88-95% in Day 1 samples for the 2.34, 4.69, and 9.37 ppm a.i. treatment levels, 91-95% in Day 2 samples for the nominal 2.34 and 4.69 ppm a.i. treatment levels, and 90-95% in Day 4 samples 2.34 and 4.69 ppm a.i. treatment levels, with no pattern of decline (7.5 Appendix E, p. 24). The nominal 9.37 ppm a.i. treatment group was only analytically verified on Day 0 and 1 and the 18.7 ppm a.i. treatment group was only verified on Day 0 due to 100% mortality by day 1 and 0, respectively. The LOQ was 0.01 ppm a.i. (p. 24).

Storage conditions of test chemicals: The test chemical was stored at room temperature.

Water Solubility: 29 mg/L (deionized water at 20°C)
OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound. All OECD requirements were not reported.

2. **Test organism**:

Species: Rainbow trout (*Oncorhynchus mykiss*)

Age at test initiation: Not reported

Weight at test initiation: 1.26 ± 0.28 g (average at study start)

Length at test initiation: 4.80 ± 0.29 cm (average at study start)

Source: Linn, Lennestadt, Germany

B. STUDY DESIGN:

1. **Experimental Conditions**

a. Range-finding Study: A range-finding study was not conducted.

b. Definitive Study:

Table 1 . Experimental Parameters

Parameter	Details	Remarks Criteria
Acclimation period:	Continuous (observed for at least 14 days).	
Conditions: (same as test or not)	Same as test	
Feeding:	Trout fish diet was provided, except during the 48 hours prior to testing.	*EPA requires: minimum 14 days; no feeding during test OECD requires minimum of 12 days.*
Health: (any mortality observed)	Mortality was <5% prior to testing.	
Duration of the test	96 hours	*EPA/OECD requires: 96 hours*
Test condition static/flow through	Static	
Type of dilution system- for flow through method.	N/A	*EPA: Must provide reproducible supply of toxicant, with a consistent flow rate of 5-10 vol/24 hours, and meter systems calibrated before study and checked twice daily during test period*
Renewal rate for static renewal	N/A	

Parameter	Details	Remarks Criteria
Aeration, if any	Dilution water was aerated prior to use in the study. It was not reported whether or not aeration was used during the exposure period.	*EPA requires: no aeration; OECD permits aeration*
Test vessel Material: (glass/stainless steel) Size: Fill volume:	Not reported	*EPA requires: Size 19 L (5 gal) or 30 x 60 x 30 cm* *Fill volume: 15-30 L of solution*
Source of dilution water	The dilution water was reconstituted water (salt stock solutions were added to demineralized water). The water was aerated prior to testing.	Results of analysis of the diluent water supply (April 18, 1990) for various parameters including metals, pesticides, and contaminants are provided in Appendices C-E, pp. 21-23. *EPA 1975; Soft reconstituted water or water from a natural source, **not** dechlorinated tap water;* *OECD permits dechlorinated tap water.*

Parameter	Details	Remarks Criteria
Water parameters: Hardness pH Dissolved oxygen	40-60 mg $CaCO_3$/L 7.3-7.4 12.5-13.8 mg/L	The dissolved oxygen content in terms of percent saturation was not reported.
Total Organic Carbon Particulate Matter Metals Pesticides Chlorine Temperature {Salinity for marine or estuarine species} Intervals of water quality measurement	<2 ppm Not reported <LOD; See Appendix B, p. 21 <LOD <LOD 12 ± 1°C N/A DO, and pH were determined daily in each aquarium. Temperature was measured hourly.	***Hardness and pH*** *EPA requires hardness of 40-48 mg/L as $CaCO_3$ and pH of 7.2-7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline fishes; monthly range <0.8. OECD allows hardness of 10-250 mg/L as $CaCO_3$ and pH between 6 and 8.5.* ***Dissolved Oxygen*** *Renewal: ≥60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs* *Flow-through: ≥60% through out test. OECD requires at least 80% saturation value.* ***Temperature*** *EPA requires 22 ± 1 °C for estuarine/marine. OECD requires range of 21 - 25 °C for bluegill and 13-17 °C for rainbow trout.* ***Salinity*** *30-34 ‰ (parts per thousand) salinity, weekly range < 6 ‰* ***EPA water quality*** *measured at beginning of test and every 48 hours*
Concentration of test material: nominal: measured:	0 (negative control), 1.17, 2.34, 4.69, 9.37, and 18.74 ppm a.i. Mean-measured: <0.01 (<LOQ; negative control) n.m., 2.22, 4.20, 8.40, and 14.9 ppm a.i.	The 1.17 ppm a.i. treatment group was not measured (n.m.) during the exposure period. The 9.37 ppm a.i. treatment group was only measured at 0 and 1 days, and the 18.74 ppm a.i. treatment group was only measured at day 0 due to 100% mortality by day 1 and 0, respectively. *EPA/OECD requires: Control and five treatment levels. Each conc. should be 60% of the next highest conc., and should be in a geometric series*

Parameter	Details	Remarks Criteria
Solvent (type, percentage, if used)	N/A	*EPA requires: Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests; OECD requires solvent, exceed 100 mg/L.*
Number of fish/replicates: negative control: solvent control: treated:	10 fish, one replicate N/A 10 fish, one replicate	*EPA: ≥ 10/concentration; OECD requires at least 7 fish/concentration*
Biomass loading rate	0.32 g fish/L (instantaneous)	*Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day; OECD requires maximum of 1 g fish/L for static and semi-static with higher rates accepted for flow-through*
Lighting	16-hours light/8-hours dark	*EPA requires: 16 hours light/8 hours dark); OECD requires 12 -16 hours photoperiod.*
Feeding	Animals were not fed during testing.	*EPA/OECD requires: No feeding during the study*
Stability of chemical in the test system	Verified. Recoveries were 80-94% of nominal concentrations in Day 0 samples, 88-95% in Day 1samples, 91-95% in Day 2 samples, and 90-95% in Day 4 samples, with no pattern of decline (7.5 Appendix E, p. 24).	The recoveries are based on 0, 1, 2, and 4 day samples for the 2.34 and 4.69 ppm a.i. treatment groups, day 0 and 1samples for the 9.37 ppm a.i. treatment groups, and day 0 samples for the 18.7 ppm a.i. treatment groups.
Recovery of chemical Level of Quantitation Level of Detection	80-95% of nominal 0.01 ppm a.i. Not reported	Based on mean measured concentrations (7.5 Appendix E, p. 24).
Positive control {if used, indicate the chemical and concentrations}	N/A	

Parameter	Details	Remarks Criteria
Other parameters, if any	N/A	

2. Observations:

Table 2: Observations

Criteria	Details	Remarks/Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality and sub-lethal effects	
Observation intervals	4, 24, 48, 72, and 96 hours of exposure	*EPA/OECD requires: minimally every 24 hours*
Were raw data included?	Yes, sufficient	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

After 96 hours of exposure, mortality was 100% in the mean-measured 8.4 and 14.9 ppm a.i. treament groups, compared to 10% in the control (Table 1, p. 15). There were no mortalities in the nominal 1.17 (not measured), and the mean-measured 2.22 and 4.20 ppm a.i. treatment groups. The calculated 96-hour LC_{50} (with 95% C.I.) was 6.63 (4.69-9.37) ppm a.i. (based on nominal treatment concentrations).

Table 3: Effect of SXX 0665 Technical (Prothioconazole) on Mortality of Rainbow Trout (*Oncorhynchus mykiss*).

Treatment, ppm a.i. Mean-Measured and (Nominal) Concn.	No. of Fish at Start of Study	Observation Period							
		4 Hours		24 Hours		48 Hours		72-96 Hours	
		No Dead	% Mortality	No Dead	% Mortality	No Dead	% Mortality	No Dead	% Mortality
Negative control	10	0	0	0	0	0	0	1	10
x.x[a] (1.17)	10	0	0	0	0	0	0	0	0
2.22 (2.34)	10	0	0	0	0	0	0	0	0
4.20 (4.69)	10	0	0	0	0	0	0	0	0
8.4 (9.37)	10	0	0	10	100	10	100	10	100
14.9 (18.74)	10	10	100	10	100	10	100	10	100
NOAEC (mortality), ppm a.i.[b]		9.37		4.69		4.69		4.69	
LC_{50} (95% C.I.), ppm a.i.[b]		13.26 (9.37-18.74)		6.63 (4.69-9.37)		6.63 (4.69-9.37)		6.63 (4.69-9.37)	
Positive control, if used mortality: LC_{50}:		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

[a] The nominal 1.17 ppm a.i. treatment group was not measured.
[b] Based on the nominal concentrations.

B. NON-LETHAL TOXICITY ENDPOINTS:

Sub-lethal effects observed during the exposure period included fish mainly at the bottom, lying on side/back, tumbling during swimming, and convulsions (4-96 hours; Table 1, p. 15). After 96-hours of exposure, surviving fish from the mean-measured 4.20 ppm a.i. treatment group were at the bottom, lying on side/back, and tumbling during

swimming. The NOAEC and LOAEC values based on sub-lethal effects were mean-measured 2.22 and 4.20 ppm a.i., respectively.

Table 4: Sub-lethal Effects of SXX 0665 Technical (Prothioconazole) on Rainbow Trout (*Oncorhynchus mykiss*).

Treatment, ppm a.i. Mean-Measured and (Nominal) Concn.	Observation Period				
	Endpoint at 4 Hours	Endpoint at 24 Hours	Endpoint at 48 Hours	Endpoint at 72 Hours	Endpoint at 96 Hours
	% Affected	% Affected	% Affected	% Affected	% Affected
Negative control	AN	AN	AN	AN	AN
x.x[a] (1.17)	AN	AN	AN	AN	AN
2.22 (2.34)	AN	AN	AN	AN	AN
4.20 (4.69)	Fish mainly at the bottom- 100%	Fish mainly at the bottom, lying on side/back, and tumbling during swimming - 100%	Fish mainly at the bottom, lying on side/back, and tumbling during swimming - 100%	Fish mainly at the bottom, lying on side/back, and tumbling during swimming - 100%	Fish mainly at the bottom, lying on side/back, and tumbling during swimming - 100%
8.4 (9.37)	Fish mainly at the bottom, lying on side/back, and convulsing - 100%	--	--	--	--
14.9 (18.74)	--	--	--	--	–
NOAEC, ppm a.i.[b]	2.22				
LOAEC, ppm a.i.[b]	4.20				
EC_{50}, ppm a.i.	Not determined				

Treatment Level and (Nominal) Mean-Measured Concn.	Observation Period				
	% Affected Endpoint at 4 Hours	% Affected Endpoint at 24 Hours	% Affected Endpoint at 48 Hours	% Affected Endpoint at 72 Hours	% Affected Endpoint at 96 Hours
Positive control, if used % sublethal effect: EC_{50}:	N/A	N/A	N/A	N/A	N/A

[a] The nominal 1.17 ppm a.i. treatment group was not measured during the 96-hour exposure period.
[b] Reviewer converted values to reflect mean-measured treatment concentrations rather than nominal.
AN - Appeared normal.
– 100% mortality
N/A - Not applicable

C. REPORTED STATISTICS:

The 96-hour LC_{50} values was calculated using the computer program of C.E. Stephan, actual method not reported.
NOAEC and LOAEC values were visually determined, based on the observed treatment-related mortality and sub-lethal effects.
All reported toxicity values were determined using the nominal rather than the mean-measured treatment concentrations.

96-Hour
LC_{50}: 6.63 ppm a.i. 95% C.I.: 4.69-9.37 ppm a.i.
NOAEC: 2.34 ppm a.i.
LOAEC: 4.34 ppm a.i.
Endpoints affected: Mortality and sub-lethal effects
Most sensitive endpoint: Sub-lethal effects

D. VERIFICATION OF STATISTICAL RESULTS:

The 96-hour LC_{50} was determined using the binomial method via TOXANAL statistical software. The NOAEC and LOAEC values were visually determined based on the sub-lethal effects data. All toxicity values were determined using the mean-measured treatment concentrations.

96-Hour
Mortality:
LC_{50}: 5.94 ppm a.i. 95% C.I.: 4.2-8.4 ppm a.i.
NOAEC: 4.20 ppm a.i.
LOAEC: 8.4 ppm a.i.
Sub-lethal:
NOAEC: 2.22 ppm a.i.
LOAEC: 4.20 ppm a.i.
Endpoints affected: Mortality and sub-lethal effects
Most sensitive endpoint: Sub-lethal effects

E. STUDY DEFICIENCIES:

The nominal 1.17 ppm a.i. treatment level was not analytically verified at any time during the 96-hour exposure period. The reviewer does not consider this a significant deviation from U.S. EPA guideline §72-1c because identical biological results were observed at the next highest treatment level (nominal 2.34 ppm a.i.). Consequently, neither the study author or the reviewer included the nominal 1.17 ppm a.i. treatment group in any toxicity value determinations.

The study author determined all toxicity values in terms of the nominal rather than the mean-measured treatment concentrations. This deviation was also considered minor by the reviewer because toxicity values were verified in terms of the mean-measured treatment concentrations and are reported in the EXECUTIVE SUMMARY and CONCLUSION sections of this DER.

All other deviations from U.S. EPA guideline §72-1c were considered minor and did not affect the acceptability or validity of this study.

F. REVIEWER'S COMMENTS:

The results of the reviewer's statistical verification were nearly identical to those of the study author. However, the study author determined all values in terms of the nominal rather than the mean-measured treatment concentrations. Consequently, the reviewer determined toxicity values (based on mean-measured treatment concentrations; Appendix E, p. 24) are reported in the EXECUTIVE SUMMARY and CONCLUSION sections of this DER because they represent the actual treatment concentrations that fish were exposed.

The test material was observed lying at the bottom in the nominal 1.17 ppm a.i. treatment group at 0 hours, in the 2.34 ppm a.i. treatment group at 0-24 hours, in the nominal 4.69 ppm a.i. treatment group at 0-72 hours, and at 0-24 and 0 hours in the nominal 9.37 and 18.74 ppm a.i. treatment groups (test termination for the two highest treatment levels; Table 2, p. 16). The reviewer did not consider the observed precipitate to have a detrimental effect on the test species due to the fact that no effects, lethal or sub-lethal, were observed in the nominal 1.17 and 2.34 ppm a.i. treatment groups and all treatment levels were analytically verified with the exception of the 1.17 ppm a.i. group (all recoveries were 80-95% of nominal).

G. CONCLUSIONS:

This study is scientifically sound, fulfills U.S. EPA guideline §72-1c, and is classified as ACCEPTABLE. Based on the results of this study, SXX 0665 Technical is categorized as moderately toxic to Rainbow trout (*Oncorhynchus mykiss*) on an acute toxicity basis. The NOAEC based on sub-lethal effects was 2.22 ppm a.i.

96-Hour
LC_{50}: 5.94 ppm a.i. 95% C.I.: 4.2-8.4 ppm a.i.
NOAEC: 2.22 ppm a.i.
LOAEC: 4.20 ppm a.i.
Endpoints affected: Mortality and sub-lethal effects
Most sensitive endpoint: Sub-lethal effects

III. REFERENCES:

Stephan, C.E., 1982, U.S. EPA, Environmental Research Laboratory, Duluth, MN. Personal Communication to Dr. Lowell Bahner, Chairman, ASTM Task Group on Calculating LC50.

Stephan, C.E. 1977, Methods for Calculating and LC50. In: Aquatic Toxicology and Hazard Evaluation. ASTM STP 634. F.L. Meyer and J.L. Hamelink, eds. American Society for Testing and Materials. Philadelphia, PA. 65-84

APPENDIX 1. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

TOXANAL Results:

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
14.9	10	10	100	9.765625E-02
8.399999	10	10	100	9.765625E-02
4.2	10	0	0	9.765625E-02
2.22	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT **4.2 AND 8.399999 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS**, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 5.939697

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

EAD Assessment of USEPA DER

Reviewer: Émilie Larivière (#1269); PMRA **Date:** July 11, 2005

PMRA Submission Number: 2004-0843

Study Type: Acute Toxicity to Cold Water Fish (rainbow trout)

Grau, R. 1990. SXX 0665 Technical, Acute Toxicity to the Rainbow Trout in a Static Test. Unpublished study performed by Bayer AG Crop Protection Business Group, Crop Protection Development, Leverkusen, Germany, Laboratory Study No. E 2800441-9, and sponsored by Bayer CropScience, RTP, NC. Experimental start date May 14, 1990 and experimental termination date May 18, 1990. The final report issued October 26, 1990.

PMRA DATA CODE	9.5.2.1
EPA DP Barcode	D303488
OECD Data Point	8.2.1
EPA MRID	46246020
EPA Guideline	§72-1c

Reviewing Agency: US EPA

EAD Executive Summary:

The 96-hour acute toxicity of the transformation product SXX 0665 Technical (JAU6476-desthio; purity 93.7%) to rainbow trout (*Oncorhynchus mykiss*) was studied under static conditions. This study was conducted in accordance with EEC Directive 79/831, Annex V, Methods for the determination of Ecotoxicity, Method 5.1.1. Acute Toxicity for Fish (1984), OECD Guideline No. 203, and U.S. EPA Guideline 72-1 and in compliance with US EPA 40 CFR Part 160 and OECD principles of GLP. Fish were exposed to JAU6476-desthio at nominal concentrations of 0 (negative control), 1.17, 2.34, 4.69, 9.37, and 18.74 mg JAU6476-desthio/L. Mean measured concentrations were 2.22, 4.20, 8.40, and 14.9 mg JAU6476-desthio/L for the nominal 2.34, 4.69, 9.37, and 18.7 mg JAU6476-desthio/L. treatment groups, respectively.

After 96 hours of exposure, 100% mortality was observed in the 9.37 and 18.74 mg JAU6476-desthio/L treament groups, compared to 10% mortality in the control. There were no mortalities in the 1.17, 2.34, and 4.69 mg JAU6476-desthio/L treatment groups. The calculated 96-hour LC_{50} (with 95% C.I.) was 5.94 (4.20-8.40) mg JAU6476-desthio/L, which categorizes JAU6476-desthio as moderately toxic to rainbow trout (*Oncorhynchus mykiss*) on an acute toxicity basis, according to the classification scheme of the U.S. EPA (1985). Sub-lethal effects observed during the exposure period included fish mainly at the bottom, lying on side/back, tumbling during swimming, and convulsions. After 96-hours of exposure, surviving fish from the mean-

measured 4.20 mg JAU6476-desthio/L treatment group were at the bottom, lying on side/back, and tumbling during swimming. The NOEC and LOEC values based on mortality were 4.20 and 8.40 mg JAU6476-desthio/L, respectively, while the NOEC and LOEC values based on sub-lethal effects (most sensitive endpoint) were 2.22 and 4.20 mg JAU6476-desthio/L, respectively.

Results Synopsis:

Test Organism Size/Age (mean Weight or Length): Age not specified; 1.26 ± 0.28 g, 4.80 ± 0.29 cm (mean at the start of the study)
Test Type (Flow-through, Static, Static Renewal): Static

96-Hour
LC_{50}: 5.94 mg JAU6476-desthio/L 95% C.I.: 4.20-8.40 mg JAU6476-desthio/L
NOEC (mortality): 4.20 mg JAU6476-desthio/L
LOEC (mortality): 8.40 mg JAU6476-desthio/L
NOEC (sublethal effects): 2.22 mg JAU6476-desthio/L
LOEC (sublethal effects): 4.20 mg JAU6476-desthio/L
Endpoints affected: Mortality and sub-lethal effects
Most sensitive endpoint: Sub-lethal effects

Evaluator Comments:

1. The appropriate PMRA information (PMRA Submission Number, PMRA Data Code, PMRA company code, PMRA active ingredient code, PMRA use site category, OECD data point, name of PMRA secondary reviewer) was added to the EPA-DER as well as information on the chemical name (IUPAC name, CAS name and synonym) available from the PMRA Chemistry review.

2. The name Prothioconazole was removed from the title of the DER, the Executive Summary, the Methods and the Conclusions and the name JAU6476-desthio was added where appropriate, because the study was conducted with the transformation product JAU6476-desthio (SXX 0665) and not the parent compound prothioconazole.

3. Temperature data were not reported. This deviation is considered minor and does not affect the acceptability or validity of this study.

4. The PMRA reviewer agrees with the conclusions of the EPA reviewer.

Study Acceptability: This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with rainbow trout for the transformation product JAU6476-desthio. This study is classified as ACCEPTABLE.